

FILED UNDER SEAL

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

**DECLARATION OF AMIT M. PATEL IN SUPPORT OF
AZURITY PHARMACEUTICALS, INC.'S MOTION TO INTERVENE TO MOVE FOR
RECONSIDERATION OF OR APPEAL ORDER GRANTING INJUNCTIVE RELIEF**

I, Amit M. Patel, declare as follows:

1. I am currently the Chairman and Chief Executive Officer (“CEO”) for Azurity Pharmaceuticals, Inc. (“Azurity”). Silvergate Pharmaceuticals, Inc. (“Silvergate”) is wholly owned by Azurity. I refer to both collectively as “Azurity” in my declaration. My responsibilities include overseeing Azurity’s development, operational, commercial, and corporate functions, and guiding product strategy for the company’s portfolio (including Epaned®).

2. I have been the CEO of Azurity since January 2020. I have been a member of the Board of Directors of Azurity since 2018.

3. I have over twenty years of healthcare industry experience, including as Senior Vice President (“SVP”) and President of Dosage Form Solutions at Capsugel, a company that provided products and services to pharmaceutical and nutritional companies, and as Executive Vice President and Head, North America, and SVP and Head, Global Corporate Development & Strategic Planning, at Dr. Reddy’s Laboratories, Inc., a publicly-traded, global specialty-generic pharmaceutical company.

FILED UNDER SEAL

4. In my role as CEO for Azurity, [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

5. I provide the facts set forth in this declaration based on my personal knowledge and, if called as a witness, I would be able to testify to those facts.

I. AZURITY AND EPANED®

6. Azurity is a specialty pharmaceutical drug company focused on developing medication for underserved populations, namely pediatric and elderly patients. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

7. Azurity's Epaned® is an easy-to-swallow, enalapril liquid medication indicated for the treatment of hypertension, heart failure, and left ventricular dysfunction ("LVD") that is especially well-suited for pediatric and elderly patients. Epaned® has been a brand and product many years in the making. [REDACTED]

[REDACTED] Epaned® represents Azurity's unique solution to the decades-old "pill burden" associated with oral administration of solid enalapril tablets as well as the patient safety concerns that arise from compounding such oral tablets into solution. In fact, it was the first FDA-approved ready-to-use enalapril solution.

FILED UNDER SEAL

8. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

9. Azurity owns several patents directed to stable oral liquid formulations of enalapril. These include U.S. Patent Nos. 9,669,008, 9,808,442, 10,039,745, 10,154,987, 10,772,868, 10,786,482, 10,799,476, 10,918,621, 11,040,023, 11,141,405, and 11,173,141.

II. BIONPHARMA'S ABBREVIATED NEW DRUG APPLICATION & CORERX

10. Bionpharma Inc. (“Bionpharma”) filed an Abbreviated New Drug Application (“ANDA”) No. 212408, which is for a generic enalapril oral solution product to Azurity’s Epaned®. While Bionpharma’s ANDA was pending at FDA, Azurity sued Bionpharma for patent infringement by its generic drug product of several of the patents I identified above. Later, after additional patents issued, Azurity brought additional suits for Bionpharma’s infringement of the newly obtained patents. Litigation concerning Bionpharma’s infringement is ongoing.

11. Following Bionpharma’s sale of its ANDA product that was manufactured and supplied by CoreRx Inc. (“CoreRx”), Azurity sued CoreRx for patent infringement based on that manufacture and supply. Azurity sued CoreRx where it is located (M.D. Fla.) and where the rest of the dispute was already being litigated (D. Delaware). Azurity and CoreRx were able to negotiate a settlement between the parties for CoreRx’s infringement and entered into a Litigation Settlement Agreement on November 24, 2021. Ex.¹ 7. [REDACTED]

¹ Ex. refers to Exhibits in the Eli B. Richlin Declaration accompany this Declaration.

FILED UNDER SEAL

A series of 12 horizontal black bars of varying lengths, decreasing in size from top to bottom. The bars are evenly spaced and extend across the width of the frame.

12. I understand that Bionpharma has speculated that NovaQuest Capital Management L.L.C. (“Novaquest”) participated in a strategy relating to Azurity’s litigations against CoreRx and the settlement thereof. That is not true. Novaquest was not involved in Azurity’s decision to initiate litigation against CoreRx and took no positions on whether the companies pursued or reached settlement. Moreover, Bionpharma has speculated that CoreRx and Azurity are somehow working in collusion to protect one-another’s interests. This is absolutely false – both parties are only looking towards their own interests.

13. At this time, Azurity has not yet fully calculated its damages due to CoreRx's infringement prior to the date of the CoreRx Litigation Settlement Agreement. Neither Bionpharma nor CoreRx have provided their sales records to-date [REDACTED]

ANSWER

FILED UNDER SEAL

[REDACTED]

14. I understand that Bionpharma has asked this Court to order CoreRx to manufacture and supply 18,000 units for Bionpharma. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

15. Azurity has also asserted and would continue to assert that the infringement has been willful and would continue to be, if resumed. Under applicable law, a Court is likely to multiply damages up to three-times for willful infringement. Three-times the damages amounts roughly estimated above [REDACTED]

FILED UNDER SEAL

[REDACTED]

[REDACTED]

III. IMPACT OF BIONPHARMA'S AT-RISK GENERIC LAUNCH

16. Bionpharma launched its generic oral solution product to Azurity's Epaned® on or about August 16, 2021. [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

17. Because Bionpharma is no longer being supplied its generic version of enalapril maleate and barring any resumption of Bionpharma's supply or entry of another generic competitor, [REDACTED] [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

18. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

FILED UNDER SEAL

19.

20.

21.

FILED UNDER SEAL

22.

23.

A series of horizontal black bars of varying lengths, arranged vertically. The top four bars are of equal length. The fifth bar is longer than the others. The sixth bar is shorter than the others. The seventh bar is of equal length to the top four. The eighth bar is of equal length to the top four. The ninth bar is of equal length to the top four.

FILED UNDER SEAL

[REDACTED]

[REDACTED]

24. Even if Azurity is able to secure a damages judgment for the infringement of its patents by Bionpharma's generic product, I have concern that Azurity would be able to collect that judgment from either Bionpharma or CoreRx. I understand that CoreRx has represented that it would be unable to pay such damages and doubts Bionpharma's ability to indemnify it for the same, and damages would be significant. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

25. [REDACTED]

[REDACTED]

[REDACTED]

I declare under the penalty of perjury under the laws of the United States that the foregoing is true and correct.

2/2/2022

Date



Signature